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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/221,931	12/28/98	TSURUO	T WAKAB37.001A

020995 HM12/0404  
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EXAMINER

BORIN, M

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

# Office Action Summary

Application No.  
09/221,931

Applicant(s)

Tsuruo et al

Examiner

Michael Borin

Group Art Unit

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☒ Responsive to communication(s) filed on Oct 6, 2000 and 1/16/2001

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 11 and 17-21 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 11 and 17-21 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☒ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). B

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Status of Claims***

1. Amendment filed 10/06/2000 is acknowledged. Claim 11 is amended. Claim 21 is added. 11, 17-21 are pending.

### ***Information Disclosure Statement***

2. Copies of references cited in information disclosure statement has been received.

### ***Claim Rejections - 35 USC § 112, first paragraph.***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 11, 17-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 11, 21 introduce new matter as they introduce lower concentration limit of the dosage to be used in the claimed method. Specification does not describe 10  $\mu$ M as a lower concentration limit. Contrary, specification clearly teaches that  $K_i$  value is about 100 nM (i.e.,

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much lower than the newly imposed concentration limits). Applicant refers to Figure 2; however the Figure (as described on p. 10 of specification) does not set the concentration limit of 10  $\mu$ M.

***Claim Rejections - 35 U.S.C. § 102***

4. Rejection of claims 11, 17-20 under 35 U.S.C. 102(a) over Naasani et al is withdrawn in view of providing by applicant a certified copy and English translation of the priority document which satisfied the requirement for priority under 35 U.S.C. Section 120.

5. The rejection of claims 11, 17-20 under 35 U.S.C. 102(b) as anticipated by Fujiki et al. or Liao et al. or admitted prior art is provisionally withdrawn, pending the response to the rejection of the claims under 35 U.S.C. 112, first paragraph (see above). In view of the amended claim language which limits the scope of the claims to a dosage range of above 10 $\mu$ M, the following rejection is applied. The JP 910108977 reference is used to meet the dosage range limitation (even though this limitation is a subject to the rejection under 35 U.S.C. 112, first paragraph; see above).

It is known in the prior art that 1) green tea is effective as a cancer preventive, 2) catechins are known to be active ingredients of green tea or green tea extracts; 3) telomerase is active in cancer cells and is dormant in normal cells. JP 910108977 teaches that catechins obtained from green tea concentrates prevented development of colon cancer. The catechins were purified from green tea to 93% purity. The preferred concentration of catechins is 0.05-0.7% (see abstract). This dosage range reads on instantly claimed range of  $\geq 10\mu$ M. 10 $\mu$ M is equivalent to 0.29 %, as calculated using 290.3

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as the molecular weight of catechin (as provided for product #9510 in Sigma catalog). Hence, the claims are limited to dosages of  $\geq 0.29\%$ . Under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art. In the instant case, the only method step as instantly claimed is contacting cells (ie via administration) with a composition comprising a catechin. It is Examiner's position that any reference teaching exposure of cells, *in vitro* or *in vivo*, to a composition comprising catechins (e.g., green tea) in its normal and usual operation would necessarily perform the method as claimed because prevention of cancer prevents telomerase activity.

6. Rejection of claims 11, 17-20 under 35 U.S.C. 101 is withdrawn in view of applicants arguments.

***Conclusion.***

7. No claims are allowed
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March 29, 2001

**MICHAEL BORIN, PH.D**  
**PRIMARY EXAMINER**

mlb

